NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HORIZON MEDICINES LLC., and NUVO PHARMACEUTICALS (IRELAND) DESIGNATED ACTIVITY COMPANY, Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, Defendants.	**Civil Action No. 15-3324 (SRC)** **OPINION & ORDER** (consolidated for discovery purposes with Civil Action Nos. 16-4918, 16-9035, 15-3327, 16-4921, 15-3326, and 16-4920)
HORIZON MEDICINES LLC., and NUVO PHARMACEUTICALS (IRELAND) DESIGNATED ACTIVITY COMPANY, Plaintiffs, v. MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN, INC., Defendants.	
HORIZON MEDICINES LLC., and NUVO PHARMACEUTICALS (IRELAND) DESIGNATED ACTIVITY COMPANY, Plaintiffs, v. LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,	

Defendants. :
:
_____:

CHESLER, U.S.D.J.

This matter comes before this Court on the motion for summary judgment, pursuant to Federal Rule of Civil Procedure 56, by Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories (collectively, "DRL.") Plaintiffs Horizon Medicines LLC and Nuvo Pharmaceuticals (Ireland) Designated Activity Company (collectively, "Horizon") have opposed the motion. For the reasons that follow, the motion will be denied.

This motion, when filed, concerned six patents: U.S. Patent Nos. 8,852,636, 8,858,996, 8,865,190, 9,161,920, 9,188,888, and 9,345,695. When Horizon filed its opposition brief, it stated:

> After DRL filed its summary judgment papers, Plaintiffs identified claims 1-19 of U.S. Patent No. 8,858,996 (the "'996 patent") and claims 1-5, 7-9, 11-14 of U.S. Patent No. 9,161,920 (the "'920 patent") (collectively, "the Asserted Patents") to be asserted in this lawsuit.

(Pls.' Opp. Br. 1 n.1.) Plaintiffs have therefore abandoned the Complaint's claims for those patents from the six patents that do not involve the patent claims included in Plaintiffs' "Asserted Patents." This motion, then, concerns the identified claims in the Asserted Patents only. DRL moves for summary judgment that the identified claims in the Asserted Patents are invalid under the doctrine of issue preclusion, and that claim preclusion bars Plaintiffs from asserting the Asserted Patents against DRL.

In short, DRL cites the Federal Circuit's decision in Nuvo Pharm. (Ir.) Designated Activity Co. v. Dr. Reddy's Labs. Inc., 923 F.3d 1368, 1384 (Fed. Cir. 2019) ("Nuvo") and argues that Nuvo entitles DRL to a grant of summary judgment. In Nuvo, the Federal Circuit

held that all asserted claims in two patents, not at issue in this case, were invalid for lack of an adequate written description under 35 U.S.C.S. § 112. Id. DRL contends that, because the patents at issue on this motion have the same specifications as those in Nuvo, and because the claims at issue on this motion have "identical or materially the same" limitations, DRL is entitled to a grant of summary judgment. (Defs.' Br. 1-2.)

In Nuvo, the Federal Circuit held:

> Written description analyses are highly fact specific. *See Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1377 (Fed. Cir. 2017) ("[E]ach case involving the issue of written description must be decided on its own facts." Based on the specific facts of certain cases, it is unnecessary to prove that a claimed pharmaceutical compound actually achieves a certain result. But when the inventor expressly claims that result, our case law provides that that result must be supported by adequate disclosure in the specification. In this case, the inventor chose to claim the therapeutic effectiveness of uncoated PPI, but he did not adequately describe the efficacy of uncoated PPI so as to demonstrate to ordinarily skilled artisans that he possessed and actually invented what he claimed. And the evidence demonstrates that a person of ordinary skill in the art reading the specification would not have otherwise recognized, based on the disclosure of a formulation containing uncoated PPI, that it would be efficacious because he or she would not have expected uncoated PPI to raise gastric pH. Under those facts, the patent claims are invalid for lack of adequate written description pursuant to § 112, ¶ 1.

Nuvo, 923 F.3d at 1383-84 (citations omitted). This concluding paragraph demonstrates that the Federal Circuit's inquiry into the claims in the patents at issue focused on the fact that "the inventor chose to claim the therapeutic effectiveness of uncoated PPI." Id. at 1384. Thus, at the outset, this Court must examine the claims at issue in the Asserted Patents to ascertain whether they, similarly, claim the therapeutic effectiveness of uncoated PPI.

No claim in the '996 patent contains the word "effective." No claim in the '920 patent contains the word "effective." Nor does this Court discern that the plain language of the claims at issue in the Asserted Patents contains a limitation requiring the therapeutic effectiveness of uncoated PPI. Nor has DRL persuaded this Court that the claim language in the claims at issue

is materially the same as the claims at issue in Nuvo.

At this juncture, and on the present record, the difference in claim language between the claims at issue in the Asserted Patents and the claims at issue in Nuvo precludes the application of preclusion principles that DRL advocates. This decision does not bar DRL from raising these issues at trial. Instead, this decision reflects only that the present record does not support a grant of the motion for summary judgment.

As the Federal Circuit explained in Nuvo:

> Written description analyses are highly fact specific. *See Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1377 (Fed. Cir. 2017) ("[E]ach case involving the issue of written description must be decided on its own facts."

Id. Such is the case here – especially because the differences in claim language indicate that the facts may not be identical to those found in Nuvo. As Plaintiffs argue in opposition, the subject matter of the claims at issue on this motion does not, on its face, appear to be the same as the subject matter of the claims at issue in Nuvo. Nor has DRL persuaded this Court otherwise. As Plaintiffs correctly argue: "DRL's motion glosses over the fact that the Asserted Patents do not contain the same limitations requiring that the uncoated PPI be 'effective' that was the basis of the Federal Circuit's written description holding." (Pls.' Opp. Br. 12.)

In its reply brief, DRL argues:

> To overcome DRL's motion, Plaintiffs must demonstrate that the Asserted Claims raise materially different written description issues than those addressed in the Federal Circuit appeal regarding the Invalidated Patent claims. . . Mere differences in claim language are insufficient to meet this burden.

(Defs.' Reply Br. 1.) These assertions do not accurately reflect the law of summary judgment. Rule 56(a) states: "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of

law." On this motion for summary judgment, DRL, the movant, bears the burden of showing that it is entitled to judgment as a matter of law. It has not done so.

For these reasons,

IT IS on this 7th day of November, 2019

ORDERED that DRL's motion for summary judgment (Docket Entry No. 198) is **DENIED**.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.